FEB 1 6 2012

510(k) SUMMARY

ICON™ Modular Spinal Fixation System

Submitter Information

Name:	Orthofix Inc.
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Contact Person:	Natalia Volosen Senior Regulatory Affairs Specialist
Date Prepared:	January 27, 2012

Name of Device

Trade Name / Proprietary Name:	ICON™ Modular Spinal Fixation System
Common Name:	Spinal Fixation System
Product Code:	MNI, MNH, KWQ, NKB – Spinal Interlaminal Fixation Orthosis
Regulatory Classification:	Class II – 888.3060 – Spinal Interlaminal Fixation Orthosis 888.3070 Pedicle Screw Spinal System Class III – NKB code
Review Panel:	Orthopedic Device Panel (87)
Predicate Devices:	K042514 – Blackstone Modular Pedicle Screw System, SE 10-7-04 K022623 – DePuy Moss Miami Spinal System, SE 8-27-02 K031585 – U&I Optima Spinal System, SE 6-27-03 K023498 – Blackstone STS System, SE 11-13-02 K081684 – Blackstone Firebird System, SE 9-15-08

Reason for 510(k) Submission: Modifications to the ICON System

Device Description

The ICON™ Modular Spinal Fixation System is a temporary, titanium alloy, multiple component system comprised of a variety of non-sterile, single use components that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screws to the non-cervical spine. The ICON Modular Spinal Fixation System consists of multi-axial pedicle screws, mono-axial pedicle screws, reduction screws, set screws, multi-axial bodies, offset bodies, cross connectors and rods. The ICON Modular Spinal Fixation System may be used with rods, cross-connectors, hooks, spacers, staples, washers, and axial connectors from the Orthofix Spinal Fixation System. The ICON Modular Spinal Fixation System's titanium implants are not compatible with components or metal from any other manufacturer's system.

Intended Use / Indications for Use

The ICON™ Modular Spinal Fixation System is intended for posterior, non-cervical pedicle fixation. Pedicle fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft bone. The device is indicated for all of the following indications:

1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies,
2. Spondylolisthesis,
3. Trauma (i.e., fracture or dislocation),
4. Spinal stenosis
5. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. Tumor,
7. Pseudoarthrosis, and
8. Failed previous fusion

The ICON™ Modular Spinal Fixation System components may be used with certain components of the Orthofix SFS system, including rods, rod connectors and cross-connectors.

Summary of the Technological Characteristics of the Device Compared to the Selected Predicate Devices

Characteristic	Subject Device	Predicates	
Device Name	ICON™ Modular Spinal Fixation System	Blackstone Medical Modular Pedicle Screw System (K042514)	Firebird Pedicle Screw System (K081684)
Materials	Ti6Al4V Alloy	Ti6Al4V Alloy	Ti6Al4V Alloy
Screw Diameters (mm)	4.5, 5.5, 6.5, 7.5, 8.5	4.5, 5.5, 6.5, 7.5, 8.5	4.5, 5.5, 6.5, 7.5, 8.5
Screw Lengths	25-80mm	25-80mm	25-110mm
Rod Diameters	5.5mm	5.5mm	5.5mm
Rod Diameters	Straight and curved (radii range from 4.42" to 6.85")	Straight and curved (radii range from 4.42" to 6.85")	Straight and curved (radii range from 4.42" to 6.85")

PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence

Characteristic	Standard / Test/ FDA Guidance
Static Compression Bending Test	ASTM F1717-04
Dynamic Compression Bending Test	ASTM F1717-04
Static Torsion	ASTM F1717-04
Static Grip Strength	ASTM F1798-97

Performance Data Summary

Mechanical testing of the Orthofix ICON™ Modular Spinal Fixation System was conducted in accordance to ASTM F1717-04 standard for Static & Dynamic Compression Bending test and Static Torsion and ASTM F1798-97 standard for grip strength. Test results demonstrated that the new, proposed changes are substantially equivalent to predicate devices that have the same intended use, similar indications, technological characteristics and principles of operation.

Basis of Substantial Equivalence

Based on mechanical performance evaluations, and equivalence in configuration, indications for use, and fundamental scientific technology, the modified ICON™ Modular Spinal Fixation System is substantially equivalent to the predicate devices. In addition, an extensive clinical comparison of experience with the ICON system compared to literature, MDR reports and FMEA evaluations indications that the ICON system is as safe and as effective as predicate devices, and is expected to perform at least as safely and effectively as the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Orthofix, Incorporated
% Ms. Natalia Volosen
Senior Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

FEB 16 2012

Re: K111448
Trade/Device Name: ICON™ Modular Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, KWQ, MNH, MNI
Dated: January 30, 2012
Received: January 31, 2012

Dear Ms. Volosen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111448
Device Name: ICON™ Modular Spinal Fixation System
Indications for Use:

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Prescription Use ___V____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

K111448